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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: John J. Connors, III, et al.

Appln. No.: 10/813,423

Filed: March 30, 2004

For: WIRE GUIDE

Attorney Docket No: 8627-452

Examiner: Rosie Yuh Loo Chang

Art Unit: 1762

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

This Paper is a Brief in support of the appeal of the final rejection of claims 1-5 in the Office action mailed March 20, 2007, as noticed in the Notice of Appeal filed July 20, 2007)

I. REAL PARTY IN INTEREST

The real party in interest is Cook Incorporated, as recorded in the Office on November 25, 2002 at Reel 013999, Frame 0865.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to the present appeal.

III. STATUS OF CLAIMS

Claims 1-5 are pending in this application. Claims 1, 2, 4, and 5 were rejected under 35 U.S.C. §102(b) as anticipated by European Patent No. 0769306 to Engelson (*Engelson*). Claim 3 was rejected under 35 U.S.C. §103 as unpatentable over *Engelson* in view of U.S. Patent No. 6,652,472 to Jafari et. al. (*Jafari*). Claims 1-5 are being appealed in conjunction with this brief.

IV. STATUS OF AMENDMENTS

An after final amendment was filed by Appellant on May 21, 2007 in this application after the March 20, 2007 mailing date of the final action. Although not indicated on form PTOL-303, the Examiner has indicated in the attached sheets the applicants arguments were fully considered and, therefore, Applicants submit that the Reply Under 37 C.F.R. 1.116 was entered by the Examiner.

V. SUMMARY OF THE INVENTION

The invention embodied in the rejected claims provides a method for making a lubricious wire guide 100 having improved handling ability, as shown in Figure 1. A mandrel 101 having a proximal portion 105 and a distal portion 107 is provided. A first coating 103 with a low coefficient friction is applied over the mandrel 101. The first coating 103 is removed from the distal portion 107 of the mandrel 101. A coil 115 may then be connected to the distal portion 107 of the mandrel 101. A second coating 113 is applied over the distal portion 107 of the mandrel, where the second coating 113 provides a sub-structure. Next, a third coating 109 is applied over the first coating 103, where the third coating 109 comprises a surface that allows for easy maneuverability of the wire guide 100. This process is shown graphically in the flowchart of Figure 2.

VI. ISSUE

Whether the Examiner failed to make a prima facie case of anticipation, in view of the Examiner's failure to show that the cited references teach removing the first coating from the distal portion of the mandrel.

VII. ARGUMENT

Claims 1, 2, 4 and 5 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by European Patent No. 0,769,306 to Engelson (*Engelson*).

Engelson does not teach each and every element of the claimed invention. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. For example, each of claims 1 and 5 recite the steps of applying a first coating over a mandrel having a proximal portion and a distal portion, and *removing the first coating from the distal portion of the mandrel*. Contrarily, *Engelson* teaches the application of a first coating solely over the proximal region of a mandrel rather than over both a proximal portion and a distal portion the mandrel. As such, *Engelson* fails to teach removing the first coating from the distal portion of the mandrel.

When discussing the *Engelson* reference, it may be helpful to understand the terminology applied to the different elements applied to the wire guide. Figure 1 illustrates a wire guide with a wire guide core 104 having a proximal portion 102 and a distal portion 106. The proximal portion 102 has a fluorocarbon polymer coating 103 (corresponding to the first layer in the Examiner's analysis). Further, the wire guide core 104 includes a distal portion 106 having a tie layer 110 (corresponding to the second layer in the Examiner's analysis) and a hydrophilic layer 108 (corresponding to the third layer in the Examiner's analysis).

The Examiner's reasons for maintaining the rejections to claims 1, 2, 4, and 5 are improper (see page 3 of the Detailed Action). *Engelson* only teaches that the guidewire (100) "has a more proximal region (102) having a permanent, spray-applied coating (103) of a fluorocarbon polymer, e.g., a polytetrafluoroethylene such as a Teflon, or other thin tough lubricious polymer such as polyarylenes or polysulfones applied directly onto the core wire (104) and a more-distal region (106) adjacent to the more-proximal region (102)" (*Engelson*, column 5, lines 9-16) and that the "coating (103) on the more proximal portion (102) is adjacent the coatings (108) and (110) on the more distal section (106)." (*Engelson*, column 7, lines 57-column 8, line 1). However, on page 3 of the Detailed Action, the Examiner improperly states that some of the first coating would inherently be sprayed on the distal portion because *Engelson* does not take any extra effort such as masking the distal portion to coat solely over the proximal portion. The Examiner must provide rationale or evidence tending to show inherency. M.P.E.P. §2112. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *Id.* To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745; 49 U.S.P.Q. 2d 1949, 1950-51 (Fed.Cir.1999). Here, the Examiner has not provided evidence or rationale that the first coating would be sprayed on the distal portion. Rather, the Examiner simply relies on *Engelson's* lack of disclosure to solely coat the proximal portion of the guide wire. The mere possibility that coating the distal portion may occur based on an absence of a masking step is not sufficient.

Moreover, the Applicants respectfully disagree that it would be inherent to remove any undesired coating, including the first coating from the distal portion, as argued by the Examiner. The Examiner relies on the reasoning that the cleaning procedure taught by *Engelson* would inherently remove any undesired coating on the distal portion. Detailed Action, Page 3. However, the Applicants respectfully submit that “the mere fact that a certain thing may result from a given set of circumstances is not sufficient” and “[i]nherency may not be established by probabilities or possibilities.” See *In re Robertson*, 169 F.3d 743, 745; 49 U.S.P.Q. 2d 1949, 1950-51 (Fed.Cir.1999). Here, the mere possibility that a subsequent cleaning would remove any undesired coating is not sufficient. The Examiner has not made it clear how a cleaning procedure would inherently remove any undesired coating on the distal portion. Rather, the Examiner improperly states the argument as a conclusion.

Furthermore, the Applicants believe that the Examiner has misinterpreted the teaching in *Engelson*. The Examiner states that *Engelson* teaches “applying first coating on the majority of its length located proximally by spraying the coating over mandrel having a proximal portion and a distal portion.” However, “[t]he guide wire (100) typically has a total length typically between about 50 and 300 centimeters” and “[t]he relatively more flexible distal section (106) extends for 3 to 45 centimeters or more of the distal end of the guide wire (100).” *Engelson*, column 5, lines 30-36. Although the Examiner may be correct that the first coating in *Engelson* is applied on the majority of the length of the mandrel, it is only because the majority of the length of the mandrel is its proximal section 102 while merely 3 to 45 centimeters encompasses the length of the more flexible distal section 106 of the guide wire 100. Column 5, lines 30-36.

Moreover, although *Engelson* may or may not take any extra effort such as masking the distal portion in order to coat solely over the proximal portion thereof, *Engelson* still fails to teach applying a first coating over the distal portion of the mandrel. Any coating of the non-hydrophilic lubricious polymer on the distal portion would be by mere accident and is not taught in *Engelson*. Furthermore, whether or not the cleaning procedure would remove any undesired coating is non-responsive to the Applicants' argument that *Engelson* fails to teach each and every element of the invention as claimed in the present application.

Further, the Examiner's assertion that *Engelson* teaches the step of removing the first coating from the distal portion of the mandrel is misplaced. Since *Engelson* fails to disclose the application of a first coating to the distal portion of the mandrel, *Engelson* cannot possibly disclose the removal of such coating from the distal portion of the mandrel as recited in claims 1 and 5. The procedure to remove the first coating from the distal portion of the mandrel the Examiner refers to is merely a cleaning process to prepare the metal surface of the wire guide core, for the application of a hydrophilic polymer rather than a process for removing a first coating from the distal portion of the mandrel. (*Engelson*, column 10, lines 10-15). Specifically, line 15 details the procedure described in lines 9-15, the procedure is as follows "the *wire guide core* is placed in the plasma chamber and cleaned with an oxygen plasma etch. The *wire guide core* is then exposed to a hydrocarbon plasma to deposit a plasma polymized tie layer on the layer guide core to complete the pretreatment." (Emphasis added). As such, it is clear that the oxygen plasma etch cleaning happens prior to the deposition of either the tie layer 110 or the hydrophilic layer 109. In addition, *Engelson* requires that the *wire guide core* is exposed to a hydrocarbon plasma. *Engelson* refers to the wire guide core 104 synonymously with

core wire 104. Specifically, the material making up the core wire 104 may be 303, 304, 304b or 316 stainless steel. (Column 5, lines 48-54). Each additional coating is referred to by a separate reference number apart from the wire guide core 104. As such, it can be understood that the steel surface of the wire guide core is what is being cleaned by the oxygen plasma etch, rather than an applied coating being removed by the oxygen plasma etch. *Engelson* discloses that the guidewire core is "cleaned with an oxygen plasma etch," and a "plasma-polymerized tie layer" is deposited "on the guidewire core to complete the pretreatment." (Column 10, lines 16-20). *Engelson* further discloses that "the pretreated guidewire may then be coated by a hydrophilic polymer." (Column 10, lines 48-49). However, *Engelson* does not disclose the steps of applying a first coating to a mandrel and *removing* the first coating from the distal portion of the mandrel. Hence, *Engelson* fails to teach each and every element of the claimed invention.

Accordingly, reconsideration of the rejections under 35 U.S.C. §102(b) and the allowance of claims 1 and 5 are respectfully requested.

Further since claims 2 and 4 depend generally from claim 1, the reasons for allowance of claim 1 apply as well to the dependent claims.

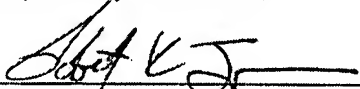
Claim 3 has been rejected under 35 U.S.C. §103(a) as being unpatentable over *Engelson* in view of U.S. Patent No. 6,652,472 to Jafari et al. (*Jafari*). *Jafari* does not teach the elements note above as missing from *Engelson*. Since claim 3 generally depends from claim 1, the reasons given above in support of claim 1 are equally applicable to claim 3. Accordingly, reconsideration and a withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

FEES

The Commissioner is hereby authorized to charge a briefing fee of \$500.00 pursuant to 37 C.F.R. § 1.17(c), along with any fee deficiency associated with the filing of this Paper, to Deposit Account No. 23-1925.

Respectfully submitted,

September 20, 2007
Date



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RKF/slk

Attachment: Appendix of Claims on Appeal

IX. APPENDIX - CLAIMS ON APPEAL

1. A method for making a wire guide comprising:
providing a mandrel having a proximal portion and a distal portion;
applying a first coating having a low coefficient friction over the
mandrel;
removing the first coating from the distal portion of the mandrel;
connecting a coil to the distal portion mandrel;
applying a second coating over the distal portion of the mandrel,
wherein the second coating provides a sub-structure; and
applying a third coating over the second coating, wherein the third
coating comprises a surface that allows for easy maneuverability of the wire
guide.
2. The method of Claim 1 wherein the surface comprises a polished
surface.
3. The method of Claim 1 wherein removing the first coating from the
distal portion of the mandrel further comprises forming a tapered portion on the
distal portion of the mandrel.
4. The method of Claim 1, wherein the surface allows for the easy
maneuverability of the wire guide through a vascular anatomy.
5. A method for making a wire guide comprising:
providing a mandrel having a proximal portion and a distal portion;

applying a first coating having a low coefficient friction over the mandrel;

removing the first coating from the distal portion of the mandrel;

applying a second coating over the distal portion of the mandrel, wherein the second coating provides a sub-structure; and

applying a third coating over the second coating, wherein the third coating comprises a surface that allows for easy maneuverability of the wire guide.